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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,245	02/27/2002	Michael J. Kennedy	100/14910	2024

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EXAMINER	
NAGPAUL, JYOTI	
ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/084,245	KENNEDY ET AL.	
	Examiner	Art Unit	
	Jyoti Nagpaul	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment filed on November 21, 2005 has been acknowledged. Claims 25-37 are pending.

Response to Arguments

Rejection of Claims 25-30 and 32-38 as being anticipated by Unno (US 6495104) has been modified in light of applicant's arguments.

Rejection of Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Unno in view of Schwartz (US 5547555) has been modified in light of applicant's arguments.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 25-30 and 32-37** are rejected under 35 U.S.C. 102(b) as being anticipated by Unno (US 6495104).

Unno teaches a microfluidic device. The device comprises of a base unit (330), a top unit/lid (324). The top unit/lid arranged to be removably attached to the base unit. (See Figure 3B) The top unit/lid (324) includes an exchangeable first module (328) having a plurality of cavities/electrodes (324) arranged to align with a plurality of wells/reservoirs (304) in a first microfluidic chip (300) is positioned on the base unit (330) and covered by the top unit, at least one of the first module cavities including a

pressure port. Unno recites, "a lid 324 is rotatably attached to the instrument 320. The underside of the lid 326 typically includes a number of interface elements for controlling the functioning of the device. For example, as shown, a plurality of electrodes 328 are provided attached to the underside 326 of the lid 324. These electrodes 328 rotate into communication with fluids in the reservoirs 304 in the body structure of device 300. These electrodes 328 that are operably coupled to power sources (not shown) within the instrument 320, provide actuation of material movement within the channels of the device 300 via electrokinetic forces. Although shown as electrodes 328, other interfaces are optionally or additionally provided in the lid. For example, in certain preferred aspects, one or more vacuum or **pressure ports** are provided in the lid with appropriate connectors/pressure source for interfacing with one or more reservoirs 304 of the device 300, in order to provide material movement by pressure induced flow. These vacuum or pressure ports are operably coupled to vacuum or pressure pumps disposed within the instrument 320. As shown, at least a portion of the lid 324 is **removable** and **replaceable**, in order to reconfigure the instrument to interface with a wide range of different devices. In particular, interface cassette 324a, which includes the array of electrodes 328, is removable from lid 324, and a different cassette may be inserted in its place." (See Col. 5, Lines 58-67- Col 6, Lines 1-15) Unno further discloses the device may be fabricated as an aggregation of different parts, e.g., capillaries/sipper, reaction chambers. (Col. 3, Lines 57-58) Unno further teaches a priming fluid. Unno teaches, "As used herein, a "microfluidic device" refers to a device that includes at least one fluidic element, e.g., channel, chamber, reservoir or the like,

that has at least one cross sectional dimension in the microscale range, e.g., between about 0.1 and about 1000 .mu.m. Typically, such devices include networks of channels and/or chambers that are interconnected, and through which a variety of different fluids or other materials are transported. These devices are used to mix, separate, react and otherwise manipulate sample reagents and other materials in performing a variety of chemical, biochemical and biological analyses. Microfluidic devices may be fabricated in a variety of different ways. For example, a device may be fabricated as an aggregation of different parts, e.g., capillaries, reaction chambers, etc., that are pieced together to form a desired network of channels and/or chambers. In preferred aspects however, microfluidic devices are assembled from an aggregation of planar layers to form a single integrated microfluidic device that includes the channels and chambers within its interior portion." (See Col. 3, Lines 45-64) With respect to the priming fluid, expressions relating the apparatus to contents thereof during an intended operation are of no significance in determinig patentability of the apparatus claim. (See Ex parte Thibault, 164 USPQ 666, 667 (Bd. App. 1969) Furthermore, "[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims." In re Young, 75 F.2d *>996<, 25 USPQ 69 (CCPA 1935) (as restated in In re Otto, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. **Claim 31** is rejected under 35 U.S.C. 103(a) as being unpatentable over Unno in view of Schwartz (US 5547555).

Refer above for the teachings of Unno.

Unno fails to teach a pressure block and the pressure pad.

Schwartz teaches a cartridge of reservoirs for detecting and quantifying an analyte in a sample of fluid. The cartridge comprising of a cover unit (77), a base unit

(81), flat electrode assembly/pressure block (10) and a pressure pad (30). The pressure pad made from polyethylene foam. (See Col. 11, Lines 1-2)

It would have been obvious to one of the ordinary skill in this art at the time of the invention by applicant to provide a pressure block and a pressure pad such that the microfluidic device is positioned on the pressure block and the pressure block is positioned on the resilient pressure pad in order to facilitate the function of easy removal of the microfluidic chip and also increase the efficiency of movement of fluid through the microfluidic chip.

Response to Arguments

Applicant's arguments filed on November 21, 2005 have been fully considered but they are not persuasive.

Applicant argues that Uno does not teach a system for priming a microfluidic chip that comprises a priming fluid. This argument has been addressed in the rejection above.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jyoti Nagpaul whose telephone number is 571-272-1273. The examiner can normally be reached on Monday thru Friday (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JN

Jill Warden
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